REMARKS

Reconsideration of this application in view of the above amendments and following remarks is respectfully requested. Claims 1, 4, 9, and 10 have been amended to recite that the non-biodegradable inert polymer is present in an amount of at least 35% by weight of the biguanide. Support for this amendment is found at, for example, page 12 (second paragraph from the bottom) of the specification and original claim 10. Additionally, claims 1-7, 9 ,10, 16, 19, and 20 have been amended for clarification. Claims 1-20 are currently pending and at issue.

I. Indefiniteness Rejection

Claims 9 and 10 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite. The Examiner contends that there is insufficient antecedent basis for the terms "the binary mixture of polymers" and "the mixture of three polymers." These terms have been replaced with the term "the non-biodegradable inert polymer."

Accordingly, Applicants respectfully request withdrawal of this rejection.

II. Obviousness

Claims 1-20 have been rejected under 35 U.S.C. §103(a) as obvious over Lilliott et al. (WO 01/35941) in view of Hyon et al. (U.S. Patent No. 5,100,669) and Lui (EP 440462).

Applicants respectfully traverse this rejection. The pending claims recite a multi-layer dosage form for once-a-day dosing comprising a layer of (i) a non-biodegradable inert polymer and (ii) a biguanide or a pharmaceutically acceptable salt thereof having a particle size less than 100 microns. The dosage form provides prolonged release of the biguanide resulting in improved glycemic control in diabetes patients.

Lilliott does not disclose or suggest a formulation which provides prolonged release of a biguanide. Lilliott also does not disclose or suggest a once-a-day formulation containing a biguanide.

Furthermore, claims 1, 4, and 19 of the present application recite that the non-biodegradable inert polymer is present in an amount of at least 35% by weight of the biguanide. Lilliott does not disclose or suggest that such a ratio would be desirable. In fact, the exemplified formulations in Lilliott suggest a much lower polymer content is preferred. The metformin formulations in Examples 1-4 of Lilliott have a polymer content of 15% or less, relative to the content of the biguanide metformin. This is a significantly lower polymer content than in the biguanide-containing layer of the multilayer dosage form of the presently claimed invention.

Additionally, the Examiner has acknowledged that Lilliott is "silent as to the particle size of the drug particles" (p. 4, first line of the Office Action).

According to the Examiner, Hyon teaches microparticles of antidiabetic agents. As discussed below, Hyon does not disclose or suggest a once-a-day multi-layer dosage form containing a biguanide.

Hyon discloses microspheres of polylactic acid and a water soluble physiologically active substance. According to Hyon, these microspheres release 30% or less of the active substance after 24 hours in an *in vitro* elution test (see abstract and col. 3, lines 2-8), and "can gradually release the active substance for a long time of period of more than one week" (see abstract, and col. 7, lines 20-21). In other words, the microspheres of Hyon release the encapsulated drug over a period of a week or longer, and therefore are not suitable for a once-a-day formulation as presently claimed. For this reason, Hyon also clearly teaches away from a formulation which releases 25-45% of the biguanide within 1 hour as recited in pending claim 14.

The Examiner has cited Lui for its disclosure of the viscosity of certain components such as hydroxypropyl cellulose ethers. Liu is solely directed to an ibuprofen formulation. Liu, therefore, does not disclose or suggest a biguanide formulation, let alone one containing a second active agent as well, as recited in the pending claims.

For the foregoing reasons, Lilliott alone or in combination with Hyon and Liu fails to render obvious the presently claimed invention. Accordingly, Applicants respectfully request withdrawal of this rejection.

III. Conclusion

Favorable consideration on the merits and prompt allowance are respectfully requested. In the event any questions arise regarding this communication or the application in general, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Dated: December 9, 2009

Respectfully submitted,

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